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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/668,840 | 09/23/2003 | Paul Alfred Dickinson | CARP-0108 | 4976 |

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| EXAMINER | |
|---|---|
| GOLLAMUDI, SHARMILA S | |
| **ART UNIT** | **PAPER NUMBER** |
| 1616 | |

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/668,840 | DICKINSON ET AL. | |
| | Examiner | Art Unit | |
| | Sharmila S. Gollamudi | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *36- 65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36- 65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/647331.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Receipt of Amendments and Arguments received on October 24, 2005 is acknowledged. Claims 36- 65 are pending in this application.

### *Claim Rejections - 35 USC § 112*

The rejection of claims 37, 40, 47-48, 52, 55, and 62-63 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of applicant's amendment to 40, 4,7 and 62 and applicant's arguments with regard to claims 37, 48, 52, and 63.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**The rejection of claims 36-65 under 35 U.S.C. 102(b) as being anticipated by US patent 5,725,841 to Duan et al is maintained.**

Duan et al discloses an aerosol formulation containing a particulate drug, a propellant, and a dispersing aid derived from a hydroxyacid, mercapto acid, or an amino acid, wherein the formulation does not flocculate, cream, or settle quickly. See abstract and column 2, lines 6-20.

The amino acid derivative has the general formula described on column 3, lines 50-55 and column 6, lines 17-45. The most preferred amino acid residues include glycine, valine, leucine, serine, etc. . see column 6, lines 48-55. The dispersing aid is used in a concentration of

0.001 to 1 part based on 100 parts by weight of the propellant. The examples contained a concentration of 0.05% of the dispersing agent. See examples 35-38.

The propellant of choice is instant HFC-143a (1,1,1,2-tetraflurothane or HFC-227 (1,1,1,2,3,3,3-heptafluropropane). Duan et al discloses the instant drugs 38, 48, 52, and 63. see column 8, lines 22-35 and examples.

The formulations are be prepared by combining (i) the drug in an amount sufficient to provide a plurality of therapeutically effective doses; (ii) the dispersing aid; (iii) the propellant in an amount sufficient to propel a plurality of doses from an aerosol canister; and (iv) any further optional components; and dispersing the components. The components can be dispersed using a conventional mixer or homogenizer, by shaking, or by ultrasonic energy. See column 10, lines 20-35. Duan discloses metered dose valves on aerosol canisters to deliver the formulations. See column 10, lines 35-40.

Lastly, Duan discloses the formulations can be delivered to the respiratory tract and/or lung by oral inhalation in order to effect bronchodilation or in order to treat a condition susceptible of treatment by inhalation, e.g., asthma, chronic obstructive pulmonary disease. The formulations of the invention can also be delivered by nasal inhalation in order to treat, e.g., allergic rhinitis, rhinitis, or diabetes. See column 10, lines 59-65.

***Response to Arguments***

Duan et al disclose a particulate drug and dispersing aid "derived from a hydroxacid, mercapto acid, or an amino acid." Applicant argues that "by derived from" Duan means that the hydroxyacid, mercapto acid or amino acid must be in the form of linear, branched or cyclic chains, comprising between 3 and about 40 monomer units. Applicant argues Duan does not

teach the use of amino acids and amino acid derivatives as used in the application, but only the use of polypeptides, i.e., amino acid chains.

Applicant's arguments filed 10/24/05 have been fully considered but they are not persuasive. Firstly, applicant's arguments "that the claims of U.S. 6,136,294 from which the instant claims were copied, were found to be patentable over Duan presumably for this reason" is irrelevant since each application is prosecuted independently and separately. Further, the examiner cannot presume the prosecution history of another patent and can only reply to arguments pertaining to the present application, which are found to be unpersuasive.

With regard to applicant's argument that the instant amino acids claimed are different from Duan et al, the examiner points out that applicant has broadly claimed "amino acid and amino acid derivatives". Duan discloses that the dispersing agent is derived from an amino acid, in essence, this is a amino acid derivative. Therefore, Duan reads on the instantly claimed amino acid derivative.

With regard to applicant's argument that Duan does not teach "the amino acid as used herein" is unpersuasive since it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, the examiner notes that the instant specification does not explicitly define the term "amino acid derivative" and thus cannot fall back on the specification to define the term.

For the reasons above, Duan is considered to anticipate the instant claims.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**The rejection of claims 36-37, 39-48, 50-52, 55-63, and 65 under 35 U.S.C. 102(e) as being anticipated by US patent 6,655,379 to Clark et al is maintained.**

Clark et al disclose an aerosolized active agent delivery, which may be formulated into a dry powder, a nebulizer, or admixed with a propellant. See abstract. The active agent may be dissolved or suspended in the propellant. Clark incorporates US patent 5,672,581 to teach the propellant system. See column 7, lines 15-20. Clark also discloses the use of metered dose inhalers. See column 7, lines 60-67.

Instant active agents (albuterol, budesonide, flunisolide) are disclosed on column 4, lines 54-60 and example 5. Clark discloses the use of pharmaceutical carriers to improve the dispersibility of the powder within the device to provide for a more efficient and reproducible delivery of the active agent. Amino acids including glycine, arginine, lysine, etc. and peptides (HSA and gelatin) are taught as carriers with glycine and HSA (human serum albumin) being preferred. See column 6, lines 36-65.

Clark discloses combining glycine or HAS to prepare the active agent. HAS is used in an amount of 6.75% with heparin. See column 9 in its entirety. The amorphous powder is then used as a dry powder, a nebulizer, or suspended in a propellant.

Lastly, Clark et al discloses delivery of insulin to the lungs to treat diabetes. See column 2, lines 49-55.

It should be noted that HAS is a protein that inherently contains amino acids and thus reads on applicant's amino acid enhancing material.

It should be noted that Clark et al is given priority to 3/16/98 wherein the subject matter of US '379 is fully supported by the provisional applications.

***Response to Arguments***

Applicant argues that Clark is only directed to dry powder active formulations and not aerosolized particles in a particulate admixture with a propellant. Applicant argues that Clark does not teach the claimed use of the amino acid to enhance suspension quality.

Applicant's arguments filed 10/24/05 have been fully considered but they are not persuasive. The examiner points out that Clark discloses an aerosolized formulation on column 3, lines 1-5 and column 5, lines 19-25. On column 3 Clarks discloses delivery "active agent formulations suitable for use in the present invention include dry powders, solutions. suspensions or slurries for nebulization and particles suspended or dissolved within a propellant." Lastly, Clarks discloses amino acids to improve the dispersiblity of the active agent. The examiner points that the prior art need only disclose the amino acid and does not need to recognize every property that it imparts in the composition, i.e. its "suspension enhancing quality", to anticipate the instant invention. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

For the reasons above, Clark is considered to anticipate the instant claims.

***Conclusion***

None of the claims are allowed at this time.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER